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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,313	10/22/2001	Stanley T. Crooke	ISPH-0613	5314

7590 10/09/2003

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,313	CROOKE ET AL.	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, and 22, drawn to an RNase H polypeptide that may be an RNase HI or type 2 RNase H polypeptide and compositions comprising pharmaceutical carriers or antisense and said RNase H, classified for example in class 435, subclass 183.

II. Claims 14-19, 24-26, 44 and 45 drawn to an isolated polynucleotide encoding RNase H which may be RNase HI or type 2 RNase H, and compositions comprising pharmaceutical carriers or antisense with said RNase H polynucletide, and vectors and cells thereof, and methods of use, classified in class 536, subclass 23.1.

III. Claim 20, drawn to an antibody targeted to a human type 2 RNase H, classified in class 530, subclass 387.1.

IV. Claims 21, 23, and 27-36, drawn to nucleic acid probes and antisense directed to human RNase HI or human type 2 RNase H, and to methods of screening therefore, classified, for example, in class 536, subclass 24.5.

V. Claim 37-43, drawn to a method of identifying agents which increase or decrease activity of an RNase H polypeptide, classified for example in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each comprise chemical structures that are independent of one another and not disclosed as capable of use together, and have different modes of operation. The polypeptide of Group I is not disclosed as being used in any method with either the polynucleotide of Group II, or the antibody of Group III. Similarly, the polynucleotide of Group II is not disclosed as being used with the antibody of Group III. Furthermore, the polypeptide of Group I is an enzyme that cleaves RNA/DNA hybrids, and thus functions differently than the polynucleotide of Group II and the antibody of Group III, which are not disclosed as having catalytic activity. The antibody of Group III binds specifically to molecules based on complex tertiary structure, a feature not shared by the polynucleotide of Group II.

Furthermore, the antisense of Group IV is unrelated to the polynucleotide of Group II and the antibody of Group III, because the antisense molecules of Group IV are not disclosed as being used in any method with the polynucleotide of Group II and the antibody of Group III. Furthermore, the antisense of Group IV binds to complementary strands of RNA, which is not a disclosed mode of operation for either the polynucleotide of Group II and the antibody of Group III. Finally the method of Group V of identifying agents that increase or decrease activity of an RNase H polypeptide is drawn to screening a broad class of agents that include small molecule inhibitors, and involves steps such as measuring the activity of RNase H that are not shared with any other groups.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any of the above listed Groups is not required for any other Group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD

Karen A. Lacourciere

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER